SA Health

Streamline Non-Formulary Approval: Infliximab 100mg injection

Additional dosing of infliximab is available via Streamline Non-Formulary Approval for Gastroenterology inpatients for the treatment of acute severe ulcerative colitis (ASUC) who have an incomplete response to the initial induction dose (5mg/kg). This form covers an accelerated infliximab induction dose.

☐ Patients with an inadequate response (>4 stools daily and/or ongoing rectal bleeding and/or CRP>45) can be prescribed an additional (early) infliximab dose of **5-10mg/kg 72 hours <u>after</u> their initial induction dose** if the treating team do not judge colectomy to be indicated at that point. Refer to locally approved protocols.

In those in whom ASUC responds to this 72-hour dose (as above), where colectomy is avoided, a third infliximab dose 4 weeks later is recommended.

The following information is required to be provided by the prescriber prior to dispensing.

Patient details:

Name:		
UR #:	Date of birth:	Gender:
Patient location (site/hospital):		

Prescriber eligibility for Infliximab accelerated dosing in ASUC:

☐ Gastroenterologist specialising in inflammatory bowel disease (IBD) **OR**

☐ Gastroenterology Trainee / Fellow at a recognised IBD service, after consultation with consultant gastroenterologist specialising in IBD

Patient eligibility for Infliximab accelerated dosing in ASUC:

☐ Gastroenterology inpatients with ASUC where there is an inadequate response as assessed at 72 hours post the initial infliximab dose (dose 1) **AND**

When dosage of infliximab exceeds the upper limit in the Product Information of 10mg/kg every 8 weeks:

☐ Patient has been informed that dosage of infliximab exceeds the maximum dosage in the approved Product Information of 10mg/kg every 8 weeks **AND**

☐ Documentation of the explanation given to the patient and informed consent have been recorded in the case notes **OR**

☐ Not applicable

Outcome assessment:

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Prescriber agrees to provide the following information on **discharge <u>and</u> at 12 months** after treatment:

- Was the patient prescribed oral corticosteroids? No
- Was the patient discharged on oral corticosteroids? No
    - If so, did they remain on steroids at 6 months post accelerated infliximab dosing? No
    - If so, did they remain on steroids at 12 months post accelerated infliximab dosing? No
- Did the patient require a colectomy? No

Prescriber details:

I certify that the above information is correct Date: Prescriber Name: Position:
Clinical unit, hospital:
Telephone No: Pager No:

PHARMACY USE INFORMATION

Entered in iPharmacy	Yes ☐ No ☐	Signature:
Entered in database	Yes ☐ No ☐	Date:

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